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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,474	04/20/2004	Tianmin Zhu	AM101007	7099
25291	7590	09/04/2007	EXAMINER	
WYETH PATENT LAW GROUP 5 GIRALDA FARMS MADISON, NJ 07940			FARZANEH, SHAHRZAD	
			ART UNIT	PAPER NUMBER
			1609	
			MAIL DATE	DELIVERY MODE
			09/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/828,474

Applicant(s)

ZHU ET AL.

Examiner

Shahrzad Farzaneh

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-96 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-96 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application
- ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-91 and 93, drawn to a drug-polymer conjugate having a general formula PXD (formulas I-IV) as disclosed, classified in class 424, subclass 078.
 - II. Claims 92, drawn to a method of the preparation of the drug polymer conjugate of Group I (Formula III), classified in class 424, subclass 078.
 - III. Claims 96, drawn to a method of the preparation of the drug polymer conjugate of Group I (Formula IV), classified in class 424, subclass 078.
 - IV. Claims 94 and 95, drawn to a process for the preparation of the claim 93 of Group I, classified in class 424, subclass 078.
2. Inventions I, II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the inventions of Groups II and III, the process of making the drug conjugate polymer of claim 68 (Formula III) and 74 (Formula IV) of the invention claimed in Group I, step c) discloses adding mPEG-sulphydryl 5000 to the solution of step b). Since the compound itself is claimed to have 1-1000 units for the n group, and mPEG-sulphydryl 5000 indicates a chain of 5000 units, the process can be used to make another materially different product. Furthermore, the method as claimed in the invention of Group III discloses adding an amine to the compound

Art Unit: 1609

of claim 50, in the invention of Group I. The amine group differs significantly in scope from an ethyl group, hence this method can be use to make a materially different product.

Species Election

Group I Species Election

3. This application contains claims directed to the following patentably distinct species: Formulas I, II, III, IV, and V as disclosed as drug polymer conjugates, as well as a list of pathological conditions, and agents, as disclosed in the invention of Group I. The agents are disclosed in claims 10-13, 28-31, 46-49, 64-67, and 88-91.

If Group I is chosen, Applicant is required to elect from Formula II, III, IV, V, or I as disclosed in the invention of Group I. Applicant is further required to specifically define R^1 , R^2 , R^3 , R^6 , R^7 , R^8 , and R^9 for each formula and drug-polymer conjugate as disclosed in the invention of Group I. Furthermore, Applicant is required to elect a specific pathological condition, as disclosed in the invention of Group I.

Lastly, if Group I is chosen, Applicant is required to indicate election in combination with or without an effective amount of a specific agent. If Group I is elected with an agent, a specific agent must be specified, as disclosed in the invention of Group I. The agents are disclosed in claims 10-13, 28-31, 46-49, 64-67, and 88-91.

Group IV Species Election

4. If Group IV is chosen, Applicant is required to specifically define R^1 , R^2 , R^3 , R^6 , R^7 , R^8 , and R^9 for Formula V and drug-polymer conjugate as disclosed in the invention of Group IV.

Art Unit: 1609

5. The species are independent or distinct because each disclosed formula is structurally different, hence they interact differently chemically. Furthermore, the pathological conditions as disclosed are all unrelated diseases, which require several unrelated methods of treatment. Lastly, the agents claimed in the invention of Group I are all chemically distinct and react interact differently from each other.

Applicant is required under 35 U.S.C. 121 to elect a specific single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1, 3, 9, 10, 14, 50, 68, 74, 92, 93, and 94 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

As a caution to applicant: election of a composition species that is not specifically disclosed as filed may be considered new matter.

Election/Restriction Proper

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a

Art Unit: 1609

serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include

(i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

Art Unit: 1609

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahrzad Farzaneh whose telephone number is 571-270-1557. The examiner can normally be reached on Weekly 7:30-5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1609

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SF

Ardin H. Marschel 8/30/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER